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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,874	08/06/2001	Masahiro Iwamoto	2520-0122P	7822

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EXAMINER
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WEBER, JON P

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Applicati n N .</b>	<b>Applicant(s)</b>	
	09/921,874	IWAMOTO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jon P Weber, Ph.D.	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 April 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,18 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/793,121.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> . | 6) <input type="checkbox"/> Other:  |

***Status of the Claims***

Claims 1-19 have been presented for examination.

***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-2 and 5-17 in Paper No. 5, filed 10 April 2003 is acknowledged. The traversal is on the ground(s) that there is no burden. This is not found persuasive because burden was established in the Office action of 11 October 2002 by virtue of separate classification, for example.

The requirement is still deemed proper and is therefore made FINAL. Claims 3-4 and 18-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5. It is suggested that the non-elected claims be canceled in response to this Office action to expedite prosecution.

***Specification***

This application contains sequence disclosures at page 16 that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with one or more of the requirements of 37 C.F.R. § 1.821 through 1.825 for one or more of the reasons set forth on the attached form "Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequences And/Or Amino Acid Sequence Disclosures". Wherein attention is directed to paragraph(s) §1.82 (c) and (e). Although an examination of this application on the merits can

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proceed without prior compliance, compliance with the Sequence Rules is required for the response to this Office action to be complete.

### ***Drawings***

The drawings are objected to because Figures 1-4 and 8 are of such poor quality as to be uninterpretable. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2 and 5-17 are rejected under 35 U.S.C. 112, first paragraph, for the reasons of record at pages 3-8 of the Office action of 17 December 1999 in parent application 08/793,121 because the specification, while being enabling for stimulating the proliferation of chondrocytes or the synthesis of proteoglycans *in vitro* comprising culturing the chondrocytes in the presence of a wild-type full length hepatocyte growth factor (HGF) protein, does not reasonably provide enablement for stimulating the proliferation of chondrocytes or the synthesis of proteoglycans in chondrocytes *in vivo* and the treatment therefore of cartilaginous diseases and disorders in a mammal by administration of HGF by unstated means. The specification does not enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with these claims.

Claims 1-2 and 5-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "fracture" and "bone transplantation" as cartilaginous diseases or disorders. It is unclear how a "fracture" or a "bone transplantation" could be considered as cartilaginous diseases or disorders which is not the usual meaning in the art.

**608.01(o) Basis for Claim Terminology in Description [R-14]**

The meaning of every term used in any of the claims should be apparent from the descriptive portion of the specification with clear disclosure as to its import, and in mechanical cases it should be identified in the descriptive portion of the specification by reference to the drawing, designating the part or parts therein to which the term applies. A term used in the claims may be given a special meaning in the description. No term may be given a meaning repugnant to the usual meaning of the term.

Usually the terminology of the original claims follows the nomenclature of the specification, but sometimes in amending the claims or in adding new claims, new terms are introduced that do not appear in the specification. The use of a confusing variety of terms for the same thing should not be permitted.

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The following art rejection is based upon an intervening reference filed after the Japanese priority dates of 19 August 1994 and 30 January 1995 (PCT), but before the US filing date of 21 April 1997 of parent 08/793,121. However, the Japanese priority documents have not been perfected with a certified translation into the English language so that it can be determined if the priority documents support the instantly claimed invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2 and 5-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCully (US 5,565,558).

McCully (US 5,565,558) disclose treating various human degenerative diseases associated with senescence and aging, including osteoarthritis, rheumatoid arthritis and lupus erythematosus (column 6, lines 6-28 and 54-58) with compositions which comprise, instead of interferon, hepatocyte growth factor in combination with thioretinaco ozonide. McCully (US 5,565,558) lacks all of the degenerative diseases explicitly recited instantly.

A person of ordinary skill in the art at the time the invention was made would have been motivated to administer the hepatocyte growth factor (HGF) composition of McCully (US 5,565,558) to treat other disorders instantly claimed because many of them are readily characterized as degenerative disorders associated with aging.

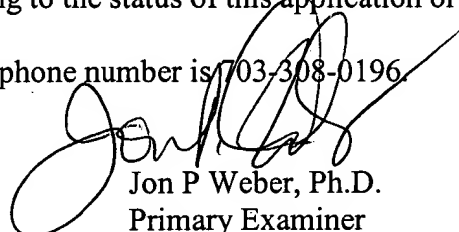
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No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 703-308-4015. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jon P Weber, Ph.D.  
Primary Examiner  
Art Unit 1651

JPW  
June 13, 2003